



GlaxoSmithKline
Attention: Olivia Pinkett, Ph.D., M.B.A.
Senior Director, GI/Inflammation US Regulatory Affairs
1250 South Collegeville Road
PO Box 5089
Collegeville, PA 19426-0989

Dear Dr. Pinkett:

Please refer to your supplemental new drug application dated September 20, 2002, received September 20, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotronex™ (alosetron hydrochloride) Tablets.

This supplemental new drug application provides for editorial changes to the Patient Physician Agreement Form and the Physician Attestation Form of the approved labeling.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted draft labeling, submitted September 20, 2002.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-107/S-007." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul E. Levine, Jr., R.Ph., Regulatory Project Manager, at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.

Director

Division of Gastrointestinal

and Coagulation Drug Products

Office of Drug Evaluation III

Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Joyce Korvick
3/20/03 04:39:55 PM
for Dr. Robert Justice